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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,200	11/03/2003	Jo-Wen Lin	525400-326	4195

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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
01/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,200	LIN, JO-WEN	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-20,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 recites the limitation "implant adjustment instrument" in line 14. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 37 states that the spinal bone implant is made of a monolithic piece of cortical bone, however, the device has not been described as "monolithic" in the specification or the drawings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 22, 24, 26-29, 32, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Shepard (US Pub. No. 2004/0078078). Shepard discloses the following of claim 21: a spinal bone implant comprising: a body (10) made of bone (paragraphs 0059-0060) and having superior (top) and inferior (bottom) surfaces for bearing against respective adjacent vertebrae defining a disc space therebetween, the body defining a plane and having spaced respective anterior (front) and posterior (back) ends defining an anterior-posterior axis in the plane, the body having an outer peripheral surface (32) and an instrument-receiving bore (44 or 46) formed in the outer peripheral surface at the anterior end, the bore extending in the region between the inferior and posterior surfaces (see Figure 2), the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore.

Shepard discloses claim 22 in claim 15 on page 6.

Shepard discloses claim 24 as shown in Figure 1.

Shepard discloses the following of claim 26: the implant of claim 21 wherein the implant has an outer peripheral wall surface, the outer peripheral wall surface having a curved portion and a flat portion, the flat portion being located on said axis at said anterior end of the implant. Please see Figures 1-9 where the peripheral surface is curved at the corners and flat along the walls.

Shepard discloses claims 27-29 as shown in Figures 1 and 2.

Shepard discloses claim 32 in paragraph 0021.

Shepard discloses the following of claim 36: a spinal bone implant comprising: a body (10) made of bone (paras. 0059-0060) and having superior and inferior surfaces for bearing against respective adjacent vertebrae defining a disc space therebetween (Fig. 2), the body defining a plane and having spaced respective anterior and posterior ends defining an anterior-posterior axis in the plane, the body having a central opening (16) in communication with the inferior and superior surfaces, the body having a curved outer peripheral surface (32) and an instrument-receiving bore (44 or 46) formed in the outer peripheral surface at the anterior end, the bore extending in the region between the inferior and superior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore (Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard in view of McKay (US Pat. No. 6,261,586). Shepard discloses the invention substantially as claimed,

however, Shepard does not teach a central opening with a blind bore. McKay teaches a bone graft that may be used in the spine which a central opening and a blind bore in col. 11, lines 1-55, where the central opening can be packed with an osteogenic composition to stimulate osteoinduction. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a central opening and a blind bore, where the central opening can be packed with an osteogenic composition to stimulate osteoinduction.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard in view of Henry et al. (US Pat. No. 5,766,252). Shepard discloses the invention substantially as claimed, however, Shepard does not teach a central opening in communication with an anterior end bore. Henry et al. teaches a spinal implant which has a central opening in communication with an anterior end bore in col. 5, lines 13-45 and col. 4, lines 29-46, where the central opening can be promote fusion by being filled with bone graft material, and the bore can be used to engage an insertion tool. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a central opening communicating with a bore, where the central opening can be filled with bone graft material to promote fusion, and the bore can be used to engage an insertion tool.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard in view of Lahille et al. (US Pat. No. 5,554,191). Shepard discloses the invention substantially as claimed, however, Shepard does not teach having roughened superior and/or inferior surfaces. Lahille et al. teaches a spinal implant which has roughened superior and inferior surfaces in col. 8, lines 35-65, for the purpose of anchoring the prosthesis in place. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

device of Shepard to have roughened superior and inferior surfaces in order to hold the prosthesis in place.

Claims 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard in view of Boyle et al. (US Pub. No. 2002/0026242). Shepard discloses the invention being made of bone, however, Shepard does not teach obtaining cortical bone from a section of the diaphysis of a long bone. Boyle et al. teaches an intervertebral implant which is made from a section of cortical bone from the diaphysis of a long bone in the abstract and paragraphs 0013 and 0041, for the purpose of utilizing the bone's intramedullary canal at serve as an opening in the implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the implant from a section of the diaphysis of a long bone in order to utilizing the bone's intramedullary canal at serve as an opening in the implant.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard. Shepard teaches the following of claim 37: a spinal bone implant comprising: a body (10) made of a piece of cortical bone (paras. 0059-0060) and having superior and inferior surfaces for bearing against respective adjacent vertebrae defining a disc space therebetween (Fig. 2), the body defining a plane and having spaced respective anterior and posterior ends defining an anterior-posterior axis in the plane, the body having an outer peripheral surface (32) and an instrument-receiving bore (44 or 46) formed in the outer peripheral surface at the anterior end, the bore extending in the region between the inferior and superior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion

instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore (Fig. 2). Shepard does not teach the implant being made of a monolithic piece of cortical bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body of Shepard out of a monolithic piece of cortical bone, since it has been held that constructing a formerly modular structure into one element involves only routine skill in the art.

Response to Arguments

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. The Applicant contends that the Shepard reference does not have an instrument - receiving bore. The claim recitations do not positively claim an instrument to be used with the spinal implant, nor do they describe any dimensions to further limit the diameter and length of the bore. Therefore, the bore of Shepard needs to only be capable of receiving a potential instrument. The bores cited above from the Shepard reference, would be fully capable of receiving an instrument, because the instrument could be utilized in the bores prior to the insertion of the pins.

Regarding the combination of the McKay and the Shepard references, the Applicant contends that they may not be combined because Shepard does not allow for the additional osteoinductive material to be received into the implant. The examiner respectfully disagrees. While Shepard allows for its non-cortical portions to impart osteoinductivity, it does not teach away from apply additional osteoinductive components into its structure. A central opening (16) may be formed into a blind bore that is dimensioned to be filled with osteoinductive material that may impart additional structural strength.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774